Organisation: Yksityinen henkilö
City: Pihtipudas
Country: Finland
Type: Individual
Public: Yes

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a. Assessment:
Others

Mielestäni tutkimus, joka tällä kyseisellä GMO maissilla on tehty, ei ole riittävän kattava koskien ihmisiä, ihmisten ja eläinten hedelmällisyyttä, imetystä ja sikiön kehitystä.

Rotat, hiiret ja kanat poikkeavat merkittävästi geneettiseltä laadultaan verrattuna niihin eläimiin (lehmä, sika) ja ihmisiin, joille tätä maissia on aikomus käyttää ravintona. Lisäksi tutkimukset ovat olleet ihmisen, lehmän ja sian eliniän huomioon ottaen hyvin lyhyitä, vain maksimissaan 90 päivän mittaisia, jolloin mm. hedelmällisyysvaikutuksia ei päästä edes vielä arvioimaan. Saatikka sitä imeytyvätkö uudet proteiinit istukan tai ihmisen maidon kautta sikiöön ja kuinka ne sikiön kehitykseen vaikuttavat.

Kattavan tutkimuksen kesto mielestäni ihmisillä ja lehmillä tulisi kestää vähintään 5 vuotta,(sioilla 2 vuotta), jolloin päästään näkemään tiinehtyvyys ja sikiön terve kehitys.

Translations

Organisation: private person
City: Pihtipudas
Country: Finland
Type: individual
Public: yes

a. Assessment:
Others

In my opinion the research, which has been done with this GMO maize, is not comprehensive enough as regards human beings, the fertility of human beings and animals, the breastfeeding or the suckling and the embryonic development.

Rats, mice and chickens are remarkably different of their genetic types compared to those animals (cow, pig) and human beings, who are going to use this maize as their nutrition. Moreover the research period has been very short considering the life time of human beings, cows and pigs, only 90 days maximum, when the fertility impacts are not possible to be estimated. It is not either known if the new proteins are absorbed into the embryo through the placenta or human milk and what kind of an influence they have to the embryonic development.

In my opinion the comprehensive research period should be at least for 5 years with human beings and cows (2 years with pigs), when it is possible to perceive the pregnancy and the healthy embryonic development.

Organisation: Individual
City: Lidingö
Country: Sweden
Type: Individual
Public: Yes

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a. Assessment:
Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

I don't understand all but I do NOT want any Gene Modified food.

Organisation: none
City: Vantaa
Country: Finland
Type: Individual
Public: Yes

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a. Assessment:
3. Environmental risk assessment

Please halt the use of genetically manipulated plants. Science is not up to the challenge. At least wait until the results from USA confirm that the bees haven't died because of genetical manipulation of plants.

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6. Labelling proposal

Listen to yourselves, not money, not profits. We are humans, not machines.

Organisation: Individual group
City: Kivijärvi
Country: Finland
Type: Individual
Public: Yes

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a. Assessment:
Others

Dear Sirs, On the plea of your desiring to act for the best of our globe I (and nine other persons) ask you to do all you are able to do and with all your might for stopping selling and cultivating all the gene manipulated cereals including maize, soya, wheat and rice, and all other gene manipulated seeds and plants, in other words, all gene manipulated cereals, vegetables, fruit and berries that are produced for eating and drinking of people and animals. We are deeply worried about the situation of our globe and, of course, about our homeland of Finland. There is not any pure food available. Everything is spoiled with poisons, chemicals, pollutants, radiation, irradiation and gene manipulation. Most of people are sick in cancers, allergies etc. It is too difficult to find pure seeds for cultivating and pure products on the shelves of shops. The life of every person is very valuable. The money must not solve all things, especially, it does not prevent things concerning true and real well-being of people (and animals). There is a part of the result of gene manipulation in sight. They have been waiting for good results but there have been just opposite effects,too. Please see, you cannot be sure what is the final result. They are trying to prevent the famine on earth, but it is possible the gene manipulated cereals will cause a global famine and dyings of people in groups, for instance, because certain gene manipulated cereals can itself make poison against noxius insects and in the same time against the pollinators. So the poison in cereals of USA is killing useful bees the most important pollinators. It is just alarming. The same poison can kill people, too, by bread but also by water, because the poison is spreading into the ground and from there into groundwaters and rivers. From where to get the bread? You surely have heard about another recent example of USA. There the cattle has been eating gene manipulated soya fodder (feed), and now they are not able to multiply. We ask, from where to get the meat? Our Great Creator has created everything good. People have already destroyed almost everything, at least, food, drinks, air, rivers, lakes, ground, soil. It would be high time to do something good for the globe by beginning from the fields and cattles and cultivating which the most important source of livelihood on the earth, so that it would not take place what the Almighty God our Creator spoke with very serious words through his prophet of Isaiah about 2800 years ago about spoiling the earth: Is. 24:3-6: The earth will be utterly emptied, and utterly laid waste; for the Lord God has spoken this word. 4. The earth mourns and fades away, the world languishes and fades away, the lofty people of the earth do languish. 5. The earth also is polluted under the inhabitants of it; because they have transgressed the laws, violated the statutes, broken the everlasting covenant. 6. Therefore has the curse devoured the earth, and those who dwell therein are found guilty: therefore the inhabitants of the earth are burned (too thin ozone layer), and few men left. It would be the best to build and not to destroy, isn´t it. Please understand. Very truly Yours Anneli Näsi, Keskustie 24, 43800 Kivijärvi, and Heikki Näsi, Anne-Mari Näsi, Tuula Lahtinen, Juha Lahtinen, Leila Jormanainen, Martti Jormanainen, Ritva Tähtivirta and Eeva-Liisa Tobiasson

Organisation: Consumer
City: Kuopio
Country: Finland
Type: Individual
Public: Yes

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a. Assessment:
Others

DNA ketjun keinotekoiset muutokset kasveissa tai muussa ei mielestäni ole perusteltuja edes ruoan tuotannon parantamiseksi nälkää kärsivienkään hyväksi. Laboratorio-olosuhteissa ja koeviljelyalueilla testattuna ei ole havaittu muodostuvan riskiä ihmiselle tai muulle. Kuitenkin tuotanto-olosuhteita on n kappaletta joissa riskin esinntymistä ei ole testattu. Myös pitkäaikaisia vaikutuksia ei vielä pystytä sanomaan. Suurin riski on tietenkin se että ko. kasvi risteytyy jonkin muun sellaisen kasvin kanssa joka voi aiheuttaa kasvin proteiineissa sellaisia muutoksia jotka ihmisen ravintoketjuun joutuessaan voi aiheuttaa esim. hullun lehmän tautia vastaavan efektin. Seuraukset huomataan vasta monen vuoden päästä.

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3. Environmental risk assessment

Kasveilla on aina taipumus risteytyä. Ympäristön kannalta suurin riski lienee se että ko. kasvi risteytyessään voi muodostaa superrikkakasvin jonka tuhoaminen voi muodostua ongelmaksi. Myös kasvin vallatessa alaa muilta luontaisilta kasveilta vaikutus voi olla ekologinen. Se voi muuttaa luontaista ravintoketjua ko. alueilla jolloin ravintoketjun yläpäässä olevat tulevat kantamaan seuraukset. Tulee tapahtumaan eliöstön yms. siirtymistä alueittain. Kasvi hajotessaan siirtää proteiinit muodossa tai toisessa maaperään jolloin myös maaperän saastumista voi tapahtua. Pitkä-aikaisena vaikutuksena voidaan ajatella että ko. kasvit köyhdyttävät alueen monimuotoisuuden ja loppujen lopuksi itse kuolevat. Tämän pohjalta myös eroosio seuraukset voi olla valtavat. Tältä pohjalta kieltäisin geenimanipuloinin koko ravintoketjun eri osa-alueilta.

Translations

Organisation: consumer
City: Kuopio
Country: Finland
Type: individual
Public: yes

a. Assessment

Others

In my opinion there are no arguments for the artificial changes of the DNA chain in plants or others not even in order to improve food production for starving people. When tests have been made in laboratories and in areas of test cultivation there have not been found any risks for human beings or others. However, there are numbers of production conditions where the risks have not been tested. The long standing influences are not yet known. The biggest risk is that a plant will cross with some other such a plant which may cause that kind of changes in the plant proteins which will cause for example a mad cow effect when getting into the nutritional chain of a human being. The consequences will be seen not until many years.

3. Environmental risk assessment

Plants always tend to cross. The biggest risk as regards the environment may be that a plant by crossing may establish a super weed whose elimination will become a problem. Also when a plant gains ground from the other natural plants the influence may be ecologic. It may change the natural nutritional chain in those areas when those ones who are on the top of the nutritional chain will bear the results. It may happen that the living organism etc. will move by areas. When a plant shatters it transfers the proteins in a form or another into the soil when also the pollution of the soil may happen. As a long standing influence may be considered that the plants will impoverish the diversity of the area and at the end they will die. On this basis also the consequences of the erosion may be huge. On this basis I would like to forbid the gene manipulation on the different parts of the whole nutritional chain.

Organisation: Greenpeace
City: Brussels
Country: Belgium
Type: Non Profit Organisation
Public: Yes

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a. Assessment:
Molecular characterisation

The transformation event 59122 contains three transgenes: (I) a 372 bp maize-optimised cry34Ab1 gene from Bacillus thuringiensis strain PS149B1; (II) a 1152 bp maize-optimised cry35Ab1 gene from Bacillus thuringiensis strain PS149B1; and (III) a 552 bp plant-optimised phosphinothricin acetyl-transferase gene (pat) from Streptomyces viridochromogenes. The proteins produced by the cry34Ab1 and cry35Ab1 genes confer together resistance against certain coleopteran insect pests. The protein produced by the pat gene confers resistance to the broad-spectrum herbicide glufosinate.

As it will be discussed below, there remain many scientific uncertainties regarding the safety of 59122-maize for the environment, human and animal health. As long as these uncertainties are not resolved, the precautionary principle should be applied and the import and use for food and feed of 59122-maize in the EU should be refused.

Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

The applicant carried out a comparison of the composition of 59122-maize grain and grain from a near isogenic non-transgenic control maize. The compositional data provided in the original application dossier were obtained from field trials carried out at six locations in Chile (Essner & Coats 2003), from field trials carried out at three locations in the USA (Buffington 2004) and from field trials at two locations in Canada (Buffington 2004). Based on the compositional data from these field trials the applicant concludes, that 59122-maize grain is comparable to grain from the near-isogenic control maize. After request from EFSA the applicant submitted further compositional data, which were obtained from field trials carried out at three locations in Bulgaria during 2003 and 2004, and from field trials carried out at three locations in Spain during 2004. EFSA used the data from field trials performed in Europe as the primary source for the comparative assessment of the composition of 59122-maize (EFSA 2007). The reason for focusing on these data remains unexplained. However, as 59122-maize is not allowed to be cultivated in EU, 59122-maize consumed by humans and animals in Europe will be imported form abroad. To date, 59122-maize is allowed for commercial cultivation in the USA and in Canada (Agbios 2007). Compositional data from field trials in Bulgaria and Spain can be used as an indication, but they give no information about the composition of 59122-maize in the actual growing regions. Therefore, the focus for the compositional assessment should be on the data derived from field trials in the USA and Canada. It is remarkable, that in its guidance document for risk assessment EFSA argues, that the comparison between GE plants and the most appropriate comparator should cover multiple geographical locations representative of the various environments in which the GE plants is cultivated (ESFA 2006). An analysis of the compositional data obtained from field trials in the USA and Canada shows, that these data are of limited value for risk assessment, mainly for two reasons. First, the field trials carried out for the production of the analysed material covered only one growing season. According to EFSA the field trials should cover more than one representative growing season (EFSA 2006). Second, not all of the compounds listed in the OECD consensus document on the comparative analysis of maize (OECD 2002) were analysed by the applicant. Recently, Herman et al. (2007) published a further compositional analysis of 59122-maize based on plant material from field trials carried out in the USA and Canada over two growing seasons. The results of this analysis showed, that the mean carbohydrate level for 59122-maize forage is statistically lower than the level in the non-transgenic control (Herman et al. 2007). In addition, it was found, that location-specific analyte levels were outside of the values reported for conventional maize for 12 of the tested compounds (forage crude fiber, grain cystine, glycine, methionine, threonine, beta-carotene, vitamin B1, delta-tocopherol, gamma-tocopherol, inositol, raffinose and phytic acid). In all cases this variability was found for the non-transgenic control maize and in most cases for the 59122-maize also.

Taken together, based on the data provided by the applicant it cannot be claimed that 59122-maize is substantial equivalent to its non-transgenic parental lines.

b. Food Safety Assessment:
Toxicology

Oral toxicity studies with the newly expressed protein To demonstrate the safety of the newly expressed proteins Cry34Ab1 and Cry35Ab1 an oral toxicity study should be performed by the applicant. In the initial application the applicant provided the results of a two-week acute oral toxicity study in mice (Brooks & DeWildt 200a, Brooks & DeWildt 2000b, Brooks & DeWildt 2000c). After request of the EFSA the applicant accomplished a repeated dose 28-day oral toxicity study in mice (ESFA 2007). In both studies no indications of adverse effects have been reported. According to the applicant it was technically infeasible to obtain sufficient quantities of high purity Cry34Ab1 and Cry35Ab1 proteins from 59122-maize to perform an oral toxicity assessment (Gao et al. 2004). Therefore the Cry34Ab1 and Cry35Ab1 proteins used in the above mentioned toxicity studies were produced in recombinant Pseudomonas fluorescens strains MR1253 and MR1256 respectively. According to EFSA guidance for risk assessment, it is essential that a microbial-derived protein used for oral toxicity studies is equivalent to the newly expressed protein as it is expressed in the GE plant (EFSA 2006). In the case of Cry35Ab1 protein, this equivalence is questionable because the amino acid sequence of the microbial derived Cry35Ab1 protein differs slightly from the amino acid sequence of the Cry35Ab1 produced in 59122-maize. Due to some PCR-primers chosen in early research stage in the development of 59122-maize four alternate amino acid residues were introduced in the microbial derived Cry35Ab1 protein (Gao et al. 2004). Taking into account these amino acid changes, it remains unclear if equivalence of microbial derived test material to Cry35Ab1 protein from 59122-maize can be established by the data provided by Gao et al. (2000), Gao & Herman (2000) and Schafer et al. (2003). These data include analysis of glycosylation, molecular weight, appearance of material in SDS-Page analysis, immunreactivity, and maldi-Tof fingerprints. In addition, toxicological studies with isolated transgene products are of limited relevance because potential pleiotropic effects in the transgenic plant as well as differences in protein quality remain unexplored.

Subchronic feeding study with grains derived from 59122-maize The applicant performed a 90-day feeding study in rats with grains from 59122-maize (Malley 2004). The statistical analysis provided by the applicant in the original study report was inadequate. Therefore EFSA requested a new analysis. This analysis revealed several statistical significant differences in haematological parameters between rats fed 59122-maize and rats fed the isogenic control line. The parameters in the 59122-maize group that were statistically significant compared to the isogenic control group were the terminal mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, red cell distribution width and absolute reticolyte values in males and terminal platelet count values in females (Malley et al. 2007). EFSA does not consider the observed differences as toxicologically relevant (EFSA 2007). EFSA argues, that the values were generally comparable with those of other control groups used in the study and/or fell within the ranges for the historical control means for rats of the same strain in other subchronic feeding studies. However, as has been shown in the MON863 maize, methods for comparing a broad set of different diets are usually not adequate for assessments of differences between a GE maize diet an a single comparable non-transgenic maize variety. In addition, it remains unclear whether the used historical control data fulfil all of the following criteria: that the historical control data were obtained with animals of the same species and strain and from the same breeder. The data were obtained in

the same laboratory, the study design, experimental methods and assessment criteria were the same, and the studies used for the comparison were carried out within a limited time window.

Allergenicity

For assessing the allergenic potential of Cry34Ab1 and Cry35Ab1 proteins the applicant takes a weight-of-evidence approach, which includes (I) an assessment of the allergenicity potential of the source of the proteins, (II) a search for homology with known protein allergens, (III) in vitro simulated digestibility studies, (IV) an evaluation of glycosylation and (V) an assessment of heat stability. Based on the results obtained by this approach the applicant concludes that the Cry34Ab1 and Cry35Ab1 proteins do not pose any significant allergenic risk to humans. EFSA shares this opinion (EFSA 2007). Based on all information made available, EFSA considers that the newly expressed Cry34Ab1 and Cry35Ab1 proteins are not likely to be allergenic. However, as will be shown below, there are several shortcomings in the assessment of the potential for allergenicity of Cry34Ab1 and Cry35Ab1 proteins.

Assessment of the allergenicity potential of Bacillus thuringiensis: An important factor to consider in assessing allergenic potential is whether the source of the genes being introduced into plants is known to be allergenic. According to the applicant as well as to EFSA Bacillus thuringiensis is not commonly known to cause allergy including occupational allergy in workers using or producing Bacillus thuringiensis products. However, neither the applicant nor EFSA discuss recent studies, which indicate at least some allergenic potential of Bacillus thuringiensis. One of these studies has been performed by Bernstein et al. (1999). They discovered that migrant health workers developed positive skin tests and elevated specific IgE and IgG antibody levels to Bacillus thuringiensis spore extracts containing Cry1Aa and Cry1Ab proteins after respiratory exposure to crop spraying. These results are not proof that Bacillus thuringiensis or Cry proteins are allergens, but they are preliminary evidence, that Bacillus thuringiensis or Cry proteins may be allergenic. Doekes et al. (2004) also found some evidence for an allergenic potential of Bacillus thuringiensis. They performed a longitudinal respiratory health study with more than 300 greenhouse workers to determine the effect of using Bacillus thuringiensis products. The presence of IgE antibodies to Bt in the blood sera suggested some workers were being sensitized to the Bacillus thuringiensis products. The authors conclude that their results may be a reason for concern that frequent use of Bacillus thuringiensis pesticides is a risk factor for occupational IgE-mediated allergic sensitization. In a further study done by Vazquez-Padron et al. (2000) the immune response induced by Cry1Ac protoxin was examined. The data obtained showed that the Cry1AC protoxin is a potent immunogen. Vazquez-Padron et al. (2000) conclude, that the high immunogenicity of Cry1A proteins administered intragastric should be taken into account before releasing Cry-containing products for human use. Furthermore, the US EPA assessed the potential allergenicity of Cry9c protein and determined that Cry9c had a medium likelihood of being an allergen (EPA 2001). Taken together, these studies are not proof that Bacillus thuringiensis or Cry proteins are allergens, but the results suggest that they could be. Therefore the assessment of the allergenic potential of 59122-maize should be done with great accuracy and not only should include indirect tests (as applied by the applicant) but also more direct tests.

Homology with known protein allergens: One step in the allergenicity assessment is the use of bioinformatics to determine whether the sequence of amino acid residues of the newly introduced proteins is similar to known allergenic proteins. The applicant conducted a search for eight amino acid strings occurring in the CRY34Ab1 and Cry35Ab1 amino acid sequences

that match strings in allergen databases (Song 2003). The selection of eight contiguous amino acids to identify matches in the databases is questionable. There are allergenic protein known, which have IgE epitopes shorter than eight amino acids (Becker 2001, Banerjee et al. 1999, Beezhold et al. 1999). Therefore FAO and WHO recommends the use of six contiguous amino acids to do the database search (FAO/WHO 2001). The applicant is aware of this recommendation, but emphasizes that the use of six amino acids would increase the chances for false positives (Song 2003). However, from a consumer safety point of view care should be taken not only to reduce false positives, but also to reduce false negatives. Moreover, a combination of methods have been proposed to reduce the false positive rate resulting from the use of six amino acids instead of eight (e.g. Kleter & Peijnenburg 2002). The six-amino-acids threshold reflects a precautionary approach, which should be taken by the applicant in his risk assessment. Generally, it has to be said, that the searches for homology have their limitation, because they are limited to sequence analysis of known allergens that are available in the database (Kuiper & Kleter 2003).

Heat stability: To test the heat stability Cry34Ab1 and Cry35Ab1 were incubated at 60, 75 and 90 for 30 minutes. After exposure to heat treatment the biological activity of the two proteins was measured in a bioassay with southern corn rootworm. The bioassay indicates that Cry34Ab1 and Cry35Ab1 are deactivated after exposure to heat, as shown by loss of biological activity (Herman 2000). The heat stability tests were performed with the Cry34Ab1 and Cry35Ab1 proteins derived from recombinant P. fluorescens.

The data submitted by the applicant refer to loss of in insecticidal activity as measured in a bioassay. The use of insecticidal activity as the parameter of heat stability is questionable, as it is implicitly assumed that insecticidal mode of action is relevant to allergenic potential, and that loss of insecticidal activity somehow correlates with loss to allergenic potential. This assumption is not consistent, because it is the size of the breakdown fragment not loss of insecticidal activity, which is of interest for potential allergenicity (Freese 2005). Loss of insecticidal activity could involve nothing more than (partial) denaturation, with little or no breakdown of the protein’s primary structure (Freese 2005). WHO and FAO recommend methods to directly measure the size of fragments resulting from the heating process; they do not mention bioassays (FAO/WHO 2001).

In vitro simulated digestibility studies: As part of the allergenicity assessment the digestibility of Cry34Ab1 and Cry35Ab1 proteins in simulated mammalian gastric fluid was investigated (Herman et al. 2003). The in vitro digestibility studies were performed with the Cry34Ab1 and Cry35Ab1 proteins derived from recombinant P. fluorescens. The two recombinant Cry-Proteins were rapidly degraded in vitro. However, it has to be stated, that the relevance of the gastric fluid assay to both in vivo digestion and allergenic potential remains uncertain and that the true predictive value of this assay is not understood (Herman et al. 2006). Therefore, there is no evidence available that the Cry34Ab1 and Cry35Ab1 proteins are degraded in vivo.

Taken together, based on the information given in the application dossier it cannot be excluded, that there is a potential allergenic risk of 59122-maize.

Nutritional assessment

To evaluate the nutritional equivalence of 59122-maize grain and non-transgenic controls the applicant performed a 42-day poultry feeding study (Delaney & Smith 2004). The statistical

analysis revealed that the liver weight in females fed with 59122-maize was significant higher than the liver weight from female fed the control diet. For Delaney & Smith (2004), the difference in liver weight is not of biological relevance because the observed values are still within the tolerance range calculated for this study. EFSA shares this opinion (EFSA 2007). After consideration of the multiplicity of the tests performed and the variability calculated from data relating to the non-transgenic control varieties, EFSA considers that the difference is unlikely to be of any biological difference. Passing over the significant difference caused by the consumption of 59122-maize with a few words of comfort should be a matter of concern (Cummins 2007).

3. Environmental risk assessment

The scope of the application includes import and processing of 59122-maize as well as its use for food and feed. Cultivation is excluded. Therefore environmental exposure to 59122-maize will be mainly restricted to the following three routes: (1) accidental spillage of grain during loading/unloading vessels, trains or truck, during transport or during processing for food and feed uses; (2) sowing seed of conventional maize or of transgenic maize other than 59122 accidentally contaminated with the 59122-event during production; (3) manure and faeces from the gastrointestinal tract of animals fed on 59122-maize. Regarding potential effects on non-target organisms the third route deserves special attention.

Exposure through manure and faces from animals fed on 59122-maize: The potential distribution of Cry protein and fragments of Cry proteins on fields through the manure of animal fed on GE Bt-plants has been documented in the scientific literature (Lutz et al. 2005, Einspanier et al. 2004, Chowdhury et al. 2003 cited by Alexander et al. 2007). Whereas the applicant does not address this exposure route at all, EFSA takes it into account in the risk assessment (EFSA 2007). However, the conclusions of the EFSA are rather an expert guess than a scientific assessment. Citing data supplied by the applicant (Herman et al. 2003) and literature on other Cry proteins (Ahmad et al. 2005, Lutz et al. 2005), EFSA concludes that most Cry proteins are degraded in the gastrointestinal tract so that very low amounts of Cry proteins remain intact to pass out in faeces. This conclusion has to be contested, because it cannot be drawn from the work cited by ESFA. The cited work done by Herman et al. (2003) is studying the stability of microbial derived Cry34Ab1 and Cry35Ab1 in a gastric fluid assay and therefore has limited significance for two reasons. First, the study was done with microbial derived Cry34Ab1 and Cry35Ab1 proteins and not with Cry34Ab1 and Cry35Ab1 proteins embedded in plant tissue. Second, the relevance of the gastric fluid assay to in vivo digestion is uncertain (Herman et al. 2006). The work of Ahmad et al. (2005) cited by EFSA does not deal with the stability of Cry proteins in the gastrointestinal tract at all. In fact, Ahamad et al. (2005) addressed the stability of Cry3Bb1 protein in soil. In turn, Lutz et al. (2005) investigated the degradation of Cry1Ab in the bovine gastrointestinal tract and showed, that fragmented Cry1Ab protein can be found in faeces. The authors conclude, that a potential effect of fragmented Cry1Ab protein to organisms is unlikely but cannot be excluded (Lutz et al. 2005). Scientific data on the stability of Cry proteins in the gastrointestinal tract of animals are scarce. The available data show that fragmented Cry proteins can be excreted by animals. Therefore, a potential distribution of Cry protein fragments on fields may be feasible considering the routine spreading of manure in e.g. dairy farms. Whether this distribution will cause any effects on non-target organisms cannot be answered, due to the fact that data on potential biological effect of fragmented Cry proteins are virtually absent. Taken together, as the applicant does not deliver any data on the fate of the Cry35Ab1 and Cry35Ab1 proteins

fed to animals, any conclusion about the risk for non-target organisms remains highly speculative. Detailed information about the fate of Cry34Ab1 and Cry35Ab1 proteins during their passage through the gastrointestinal tract should be made available.

6. Labelling proposal

Monitoring and general surveillance As it will be discussed below the plan for monitoring and general surveillance delivered by the applicant and accepted by EFSA has several shortcomings.

Post-market monitoring of food and feed According to Art. 5 83) k) of EU-Regulation 1829/2003 a post-market monitoring plan regarding the use for human consumption should be added to the dossier. Based on its risk assessment the applicant concludes that a post-market monitoring of food and feed products containing, consisting of or derived from 59122-maize is not necessary (Technical Dossier, p. 59). This opinion is shared by EFSA (ESFA 2007). However, as potential allergenicity of 59122-maize cannot be ruled out completely, it is essential that commercialized 59122-maize is monitored for the unintended occurrence of allergenic reactions. The applicant should deliver an adequate plan allowing an appropriate post-market monitoring.

Case-specific monitoring Having identified no environmental risks the applicant concludes in the Technical Part of the application dossier, that case-specific monitoring is not applicable for the use of 5922-maize for all food and feed purposes and the import and processing of 59122-maize. This opinion is shared by EFSA (ESFA 2007). In its risk assessment, EFSA considered the potential impact on non-target organisms resulting from indirect exposure to 59122-maize through manure and faeces (see above). Based on a small data set EFSA concluded that there is no risk for non-target organisms. As the case-specific monitoring has been installed for the validation of case-specific hypotheses of the risk assessment, the distribution and potential effects of Cry34Ab1 and Cry35Ab1 protein fragments on farmland should be addressed in a case-specific monitoring. The applicant should deliver an appropriate monitoring plan.

General surveillance In the general surveillance plan provided by the applicant, it is stated that a monitoring system will be used by including all the operators involved in the handling and use of viable 59122-maize. In addition substantial accidental release of viable 59122-maize will be monitored for any potential adverse effects. Furthermore, the operators will be required to report to the applicant any unanticipated effects due to environmental exposure to 59122-maize. However, the general surveillance plan of the applicant has to be considered insufficient and should be supplemented with more details: - Procedures should be specified for detection of 59122-maize unintentionally released in the environment; - It has to be specified who will be involved in the general surveillance (which institutions are involved; who is collecting the information etc); - The observatory measures should be specified; - “Hot spots” for potential dispersion of viable 59122-maize should be determined, i.e. those points along the food and feed chain where viable 59122-maize is handled, stored or transported.

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Organisation: Fondazione Diritti Genetici
City: Rome
Country: Italy
Type: Non Profit Organisation
Public: Yes

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a. Assessment:
Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

The compositional analysis shows that there are statistically significant differences in some compounds between the maize 50122 and the conventional one used as control. It may be due to some change in the biochemical pathway of the GM maize

b. Food Safety Assessment:
Toxicology

The toxicological analysis revealed statistically significant differences between rats fed the maize 59122 diet compared with the non-GM control maize. Male rats receiving the maize 59122 diet showed decreases in absolute reticulocytes count and red cells distribution width as well as increases in mean corpuscolar haemoglobin and mean corpuscolar haemoglobin concentration. Females showed an increase in platelets count. Histopathological examinations of organs revealed a statistically significant increase in uterus weight in females fed the maize 59122 diet. Furthermore, the poultry feeding study showed a liver weight higher for female broilers fed with maize 59122 diet than those fed the control diet. Considering the limits inherent the experimental design (duration and dosage) to detect unintended effects we retain these results unacceptable to prove the safety of maize 59122 for feed and food use.

Allergenicity

The potential allergenic effects are evaluated by comparison with the literature regarding the single proteins Cry34Ab1, Cry35Ab1 and PAT. We believe that more analysis (experimental analysis) should be conducted to verify the absence of any potential unintended enhancement of the allergenic potential in the GM maize 50122, because comparative analysis and toxicology showed no substantial equivalence between maize 59122 and non-GM control maize.